UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/690,825	10/18/2000	Dario C. Altieri	044574-5022-2	3716

9629 7590 05/29/2002

MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1642	10

DATE MAILED: 05/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/690,825	Altieri
Examiner	**Art Unit**
Karen Canella	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-8, 17-38, and 41-82* is/are pending in the application.

4a) Of the above, claim(s) *1-8, 19-38, and 41-59* is/are withdrawn from consideration.

5) ☒ Claim(s) *62, 63, 69, 71, and 80-82* is/are allowed.

6) ☒ Claim(s) *17, 18, 60, 61, 64-68, 70, and 72-79* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Amendment

1. Claims 39 and 40 have been canceled. Claims 17, 18, 60, 64-68, 70 and 74 have been amended. Claims 77-82 have been added. Claims 1-8, 17-38, 41-82 are pending. Claims 1-8, 19-38 and 41-59 remain withdrawn from consideration. Claims 17, 18 and 60-82 are under consideration.

2. The amendment filed January 30, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the addition of new claims 67, 68 and 70 drawn to a polypeptide comprising at least 20, 40 and 70 contiguous amino acids of SEQ ID NO:34. Applicant has given the page and line numbers to point out support in the specification for said new claims. However, the specific textual references are drawn in one case specifically to SEQ ID NO:4, which is not adequate support for the broad claim of a polypeptide comprising 20 contiguous nucleotides of SEQ ID NO:34. Furthermore, page 70, lines 26-30 discuss only the beta coiled-coil region of Survivin which is found in the last 40 amino acid residues of the full length sequence. Again this is inadequate support for the broad claims drawn to a polypeptide comprising 40 contiguous amino acids or 70 contiguous amino acids of SEQ ID NO:34.

Applicant is required to cancel the new matter in the reply to this Office Action.

3. The rejection of claims 17, 60 and 61 under 35 U.S.C. 102(e) as being anticipated by Korneluk et al (USP 6,107,041) is withdrawn.

4. The rejection of claims 18 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the Survivin protein,, does not reasonably provide enablement for homologs of SEQ ID NO:4, is maintained for reasons of record. Applicant argues that the specification defines conservatively substituted homologs of Survivin as polypeptides with amino

acid alterations that do not effect the functional activity of Survivin such as binding to its partner or inhibiting cellular apoptosis. This has been considered but not found persuasive, a the specification doe not disclose the binding partner of Survivin. One of skill in the art could not determine whether or not a conservative modification of the amino acid sequence of Survivin did indeed affect the ability of Survivin to bind to its partner without a disclosure of the identity of the binding partner. One of skill in the art would be subject to undue experimentation in order to first determine the binding partner(s) of Survivin before an evaluation of conservative variants of Survivin.

5. The rejection of claims 63-68, 70, 72 and 73 under 35 U.S.C. 112, first paragraph, for the reasons of record stated in the Office action of Paper no. 7, is withdrawn.

New Grounds of Rejection

6. Claims 17, 18, 64-68, 70, 72-79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case sets forth SEQ ID NO:34,

Claim 17 is drawn in part to the allelic variant of the polypeptide comprising SEQ ID NO:34. Claim 18 is drawn in part to conservatively substituted homologs of SEQ ID NO:34. Claim 74-76 are drawn to a mutant polypeptides comprising SEQ ID NO:34 having one or more substitutions as recited in the claims. Claims 64-68, 70 are drawn isolated polypeptides comprising 10, 15, 17, 20, 40 and 70 amino acids of SEQ ID NO:34 Claims 72, 73 and 77-79 are dependent in part on claims 64-68 and 70. The written description in this case only sets forth SEQ ID NO:34, and specific domains of the Survivin protein such as BIR domain, the B-COOH domain and SEQ ID NO:4 and therefore the written description is not commensurate in scope with the claims drawn to allelic variants of SEQ ID NO:34, conservatively substituted homologs of SEQ ID NO:34 and mutant polypeptides comprising SEQ ID NO:34 having one or more

substitutions, or polypeptides comprising 10, 15, 17, 20, 40 and 70 amino acids of SEQ ID NO:34.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.

The invention is, for purposes of the written description inquiry, whatever is now claimed. (See page 1117). The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. (See Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Reiger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined. The specification gives no disclosure, beyond the mere mention of allelic variants.

The specification sets forth residues which were substituted in Survivin to yield mutant proteins on page 63, lines 13-21. However, with the exception of the mutant produced by the substitution of Ala at residues Trp67, Pro73 and Cys84, the specification doe not define the functional activity of the resultant mutant peptides set forth in claims. With the exception of SEQ ID NO:34, the skilled artisan cannot envision the detailed structure of the mutant polypeptides, as the specification does not teach if the mutant polypeptides have full, partial, or none of the activity of the polypeptide of SEQ ID NO:34. Further claims drawn to isolated polypeptides comprising 10, 15, 17, 20, 40 and 70 amino acids of SEQ ID NO:34 do not recite a functional activity for the encompassed polypeptides. Clearly, a polypeptide comprising only 10 contiguous amino acids of SEQ ID NO:34 might not even be related to the IAP protein family or function as the disclosed Survivin. As the claims drawn to conservative and allelic variants and polypeptides comprising fragments of SEQ ID NO:34 are not limited by the function of the product,

conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Therefore, the specification does not provide adequate written description to support the multitude of proteins and peptides encompassed by claims to conservative variants or mutant proteins of SEQ ID NO:34 or isolated polypeptides comprising generic fragments of SEQ ID NO:34. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the January 5, 2001 Federal Register at Volume 66, Number 4, pages 1099-1111.

7. Claims 60 and 61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising SEQ ID NO:34 and fragments thereof retaining the ability to inhibit apoptosis, does not reasonably provide enablement for an polypeptide of IAP family which inhibits apoptosis and has a molecular weight of 16.5 KD as determined by SDS PAGE. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claims 60 is broadly drawn to any peptide of the IAP family which is able to inhibit apoptosis and has a molecular weight of 16.5. Claim 61 embodies a human polypeptide. The specification teaches only the Survivin protein having a MW of 16.5 KD, said Survivin protein being a member of the IAP family and having the ability to inhibit apoptosis. The specification teaches that Survivin is expressed in actively proliferating transformed cells, and in common human cancers in vivo, but not in adjacent normal cells. The specification teaches that amino acid sequence of Survivin, therefore one of skill in the art would known how to make Survivin and use Survivin in the diagnosis of cancer in tissue biopsies. The specification does not teach the amino acid sequences of any other IAP proteins that inhibit apoptosis. The specification does not teach the use of any other IAP proteins in the diagnosis of cancer. The scope of the claims must be commensurate with the scope of the enablement set forth, and it is clear that the specification teaches only SEQ ID NO:34, not all possible IAP proteins having the ability to inhibit apoptosis and having an apparent molecular weight of 16.5 KD as determined by SDS PAGE. Given the lack of guidance in the specification for how to

make and use other IAP polypeptides having the stated molecular weight, one of skill in the art would be subject to undue experimentation in order to practice the invention to the full scope of the claims.

8. All other rejections and objections as stated in Paper No. 7 are withdrawn.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
May 6, 2002